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No. 85-1710

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

MALLINCKRODT, INC.,
Petitioner,

v.

SAMUEL F. BENNETT, *et al.*,
Respondents.

MOTION FOR LEAVE TO FILE AND JOINT BRIEF OF SOCIETY OF NUCLEAR MEDICINE, INC. AND AMERICAN NUCLEAR SOCIETY AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

L. Manning Muntzing*
Robert J. Ross
James R. Shoemaker

Doub & Muntzing, Chartered
1875 Eye Street, N.W.
Suite 775
Washington, D.C. 20006
(202) 467-6460

Attorneys for Amici Curiae
SOCIETY OF NUCLEAR MEDICINE, INC.
AMERICAN NUCLEAR SOCIETY

Of Counsel:

James R. Heelan
Resident Counsel

AMERICAN NUCLEAR SOCIETY
555 N. Kensington Avenue
La Grange Park, IL 60525
(312) 352-6611

*Counsel of Record

CASELLAS PRESS INC. – 1717 K STREET NW WASH DC 20036 – 223-1220

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MOTION FOR LEAVE TO FILE AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

The Society of Nuclear Medicine (the "Society") and the American Nuclear Society ("ANS") respectfully move pursuant to Rule 36.1. of the Rules of this Court for leave to file a joint brief as *amici curiae* in support of the Petition for Certiorari in the above captioned case. The Society and ANS make this motion because the respondents refused to provide their written consent to the Society and ANS to participate in this case as *amici curiae* in support of the petitioner, Mallinckrodt, Inc. The Society and ANS support Mallinckrodt's Petition for Certiorari asking this Court to review the decision of the Missouri Court of Appeals that the respondents' claims for monetary damages arising out of Mallinckrodt's operation of a radiopharmaceutical processing plant are not barred by the doctrine of federal preemption.

In support of this motion, the Society and ANS state as follows:

1. The Society is a not-for-profit organization of more than 10,000 members with career interests in the diagnostic and therapeutic uses of radiopharmaceuticals. The principal activity of the Society is the development and exchange of scientific information in the field of nuclear medicine among its members and the public for the benefit of the public in general. Many of the Society's members, or the institutions for which they work, are licensed by the Nuclear Regulatory Commission.

The ANS is a not-for-profit scientific and educational organization with 14,000 individual members, including nuclear scientists and engineers, and 250 organizational members, including electric utilities and other companies and institutions licensed by the Nuclear Regulatory Commission. The principal objective of the ANS is to advance engineering and science related to atomic energy. This objective is accomplished by encouraging research, disseminating information, sponsoring meetings devoted to scientific and technical papers, setting voluntary standards, and cooperating with government agencies, educational institutions, and other organizations having similar purposes.

2. This case is of major interest to the Society, the ANS, and their members. The decision of the Missouri court, if allowed to stand, could subject members of the Society and of the ANS, or the institutions for which their members work, to potential state tort liability for federally authorized activities carried on in the ordinary course of business and in compliance with federal standards. The effect of such liability could be that the Society's members and ANS's members, or the institutions for which they

work, will be forced to curtail or abandon their work in the field of atomic energy.

3. The motion of the Society and ANS should be granted because the Society and ANS will address the effect of the Missouri court's decision on the research, development and uses of atomic energy, such as nuclear medicine and electricity generation, in our social environment, and on the persons and educational and other institutions involved in the development and use of atomic energy, a perspective and interest not otherwise represented in this case.

Wherefore, the Society and ANS request that leave to file the proposed brief be granted.

Respectfully submitted,

L. Manning Muntzing*
Robert J. Ross
James R. Shoemaker

Doub & Muntzing, Chartered
1875 Eye Street, N.W.
Suite 775
Washington, D.C. 20006
(202) 467-6460

Attorneys for Amici Curiae

SOCIETY OF NUCLEAR MEDICINE, INC.
AMERICAN NUCLEAR SOCIETY

**Counsel of Record*

Of Counsel:

James R. Heelan
Resident Counsel

AMERICAN NUCLEAR SOCIETY
555 N. Kensington Avenue
La Grange Park, IL 60525
(312) 352-6611

May 19, 1986

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JOINT BRIEF OF SOCIETY OF NUCLEAR MEDICINE, INC. AND AMERICAN NUCLEAR SOCIETY AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

The Society of Nuclear Medicine, Inc. ("Society") and the American Nuclear Society ("ANS") have filed a motion with this Court pursuant to Supreme Court Rule 36.1. for leave to file a joint brief as *amici curiae* in support of the Petition for Certiorari of Mallinckrodt, Inc., in the above captioned case. The Society and ANS filed their motion because the respondents refused to provide their written consent to the Society and ANS to participate in this case as *amici curiae* in support of the petitioner. As required by Rule 36.1., the Society and ANS are submitting this brief together with their motion.

INTEREST OF THE SOCIETY OF NUCLEAR MEDICINE AND THE AMERICAN NUCLEAR SOCIETY

The Society is a not-for-profit organization comprised of approximately 10,000 physicians, physicists, chemists, radiopharmacists, nuclear medicine technologists, and other professionals engaged in the medical uses of radioactive materials. The principal activity of the Society is the development and exchange of scientific information in the field of nuclear medicine among its members and the public.

The ANS is a not-for-profit scientific and educational organization with over 14,000 individual members, mainly nuclear scientists and engineers, and 250 organizational members, including electric utilities and nuclear laboratories. The ANS works to advance engineering and science related to atomic energy in the United States and abroad. To this end, the ANS engages in the dissemination of scientific and engineering information through publications, meetings, workshops, and conferences. In addition, the ANS encourages research in atomic energy, sets voluntary industry standards, and cooperates with government agencies, educational institutions, and other organizations involved in atomic energy activities.

The Society and ANS are interested in the present litigation because of the great impact that this case will have on the many members of the Society and of ANS who are licensed by the Nuclear Regulatory Commission (NRC), or who work for institutions licensed by the NRC, to carry on activities in the field of atomic energy, such as nuclear medicine, nuclear power generation, nuclear fuel fabrication, radioisotope production, radiopharmaceuticals manufacture, and research and development of new uses of

atomic energy. If the decision of the Missouri Court of Appeals is allowed to stand, the decision will establish a precedent that could subject members of the Society and of ANS, or the institutions for which their members work, to potential state tort liability for federally authorized activities carried on in the ordinary course of business in compliance with applicable federal standards for nuclear safety and radioactive emissions. Such potential liability could cause members of the Society and of ANS, or the institutions for which they work, to curtail or abandon their activities in the field of atomic energy. The Society and ANS believe that the federal government's pervasive regulation of radiological safety matters precludes state law tort actions for alleged radiological injuries against NRC licensees that operate in compliance with NRC safety standards.

The interests of the Society and of ANS in this case are congruent with the nation's interest. Both Congress and the Executive Branch have determined that the development and use of atomic energy for civilian applications are important to the nation, in that progress in the uses of atomic energy raises the quality of life, benefits the general welfare of the people of the United States, and strengthens national security. The Missouri court's opinion is inimical to national policy because it creates an obstacle to the continued development and use of atomic energy.

For these reasons, the Society and the ANS support the petitioner's request for this Court to review the decision of the Missouri Court of Appeals.

REASONS FOR GRANTING THE PETITION

A. Subjecting NRC Licensees to Tort Liability for Activities Carried on in Compliance with NRC Safety Standards Frustrates the Purpose and Objectives of the Atomic Energy Act and Affects Broad Public Policy Concerns.

The subjection of NRC licensees to state law tort actions for monetary damages when such licensees are operating in compliance with federal standards for radioactive emissions would frustrate one of the major purposes of the Atomic Energy Act of 1954, as amended, 42 U.S.C. §2011 *et seq.* (1982), and would affect broad public policy concerns. Congress enacted the Atomic Energy Act of 1954 to encourage private industry to participate in the development and utilization of the peaceful applications of atomic energy.[1] *E.g., Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n,* 461 U.S. 190, 221 (1983); 42 U.S.C. §2013(d). *See also Silkwood v. Kerr-McGee Corp.,* 464 U.S. 238, 281 (1984) (Powell, J., dissenting); *Duke Power Co. v. Carolina Environmental Study Group, Inc.,* 438 U.S. 59, 63 (1978). In the Atomic Energy Act Congress declared that atomic energy is capable of application for peaceful purposes, and that

> (a) the development, use, and control of atomic energy shall be directed so as to make the maximum contribution to the general welfare, . . . and

[1]Peaceful uses of atomic energy include, among other uses, the use of radioactive materials for medical purposes, the use of enriched uranium or plutonium for electricity generation, and the use of radiation as a food preservative. The term "atomic energy" is used in this brief in a broad sense to include the various peaceful uses of radioactive materials.

> (b) the development, use, and control of atomic energy shall be directed so as to promote world peace, improve the general welfare, increase the standard of living, and strengthen free competition in private enterprise. 42 U.S.C. §2011.

These declarations demonstrate Congress' intent in the Atomic Energy Act to encourage the private development and use of the peaceful applications of atomic energy for the benefit of the people of the United States.

Congress also indicated in the Atomic Energy Act its desire for the federal government to promote the peaceful applications of atomic energy by assisting private industry in developing the atom's uses. The Act states that United States funds "may be provided for the development and use of atomic energy." *Id.* §2012(g). In addition, the Act states that the federal government shall provide "a program of conducting, assisting, and fostering research and development in order to encourage maximum scientific and industrial progress" in atomic energy applications. *Id.* §2013(a). In order to "encourage scientific and industrial progress," Congress also provided for the transfer from the federal government to private industry of "unclassified scientific and technical information and for the . . . dissemination, and declassification of Restricted Data", as defined in the Act. *Id.* §2013(b). Finally, Congress intended to promote the development of atomic energy on an international scale, by "mak[ing] available to cooperating nations the benefits of peaceful applications of atomic energy. . .". *Id.* §2013(e).

In 1957, Congress continued its efforts to promote the civilian development of atomic energy by passing the Price-Anderson Act, 42 U.S.C. §2210 *et seq.* (1982), in response to private industry's concern about potential

bankrupting liability associated with the possibility of a nuclear accident. *See Silkwood v. Kerr-McGee Corp.*, 464 U.S. at 279; S. REP. No. 296, *reprinted in* 1957 U.S. CODE CONG. & AD. NEWS 1803, 1816. The Price-Anderson Act provides a comprehensive scheme of insurance and indemnity protection for persons licensed to possess nuclear materials and to operate nuclear facilities. In addition to providing protection, and thus encouragement, to private industry, the Price-Anderson Act was also intended to protect the public by assuring compensation for persons who suffer personal injury or property damage as a result of a nuclear accident. *E.g., Silkwood v. Kerr-McGee Corp.*, 464 U.S. at 279.

In order to foster an environment conducive to private development of atomic energy, Congress preempted state regulation of atomic safety matters when it enacted the Atomic Enery Act. *See, e.g., Pacific Gas & Elec. Co.*, 461 U.S. at 206-212; *Northern States Power Co. v. Minnesota*, 447 F.2d 1143, 1147-1154 (8th Cir. 1971), *aff'd*, 405 U.S. 1035 (1972). Congress was concerned that the states lacked the experience and technical knowledge to regulate atomic energy matters intelligently and effectively. G. MAZUZAN & J. WALKER, CONTROLLING THE ATOM: THE BEGINNINGS OF NUCLEAR REGULATION 1946-1962 295 (Berkeley: University of California Press 1984) [hereinafter cited as CONTROLLING THE ATOM]. Therefore, Congress vested the Atomic Energy Commission (AEC), now the Nuclear Regulatory Commission (NRC), with exclusive authority to regulate atomic safety matters. *E.g., Pacific Gas & Electric Co.*, 461 U.S. at 212.

When some states began demanding a role in atomic energy regulation, the AEC and the Joint Committee on Atomic Energy in Congress became concerned that state regulatory efforts could conflict with federal regulation

and create confusion and other obstacles that would impair the development of atomic energy. *See* CONTROLLING THE ATOM, *supra,* at 300-302. The Joint Committee thus began considering legislation to define more clearly the respective roles of the federal government and the states in regulating atomic energy. *Id.* The result was a 1959 amendment to the Atomic Energy Act, which authorized the AEC to transfer by agreement some regulatory authority over nuclear materials to any state that adopted a suitable regulatory program. 42 U.S.C. §2021. *See also Pacific Gas & Electric Co.*, 461 U.S. at 205. Section 274(b) of the Atomic Energy Act, 42 U.S.C. §2021(b), authorizes states to assume certain regulatory control over radiation hazards associated with nuclear materials, but requires state radiation protection programs to be "coordinated and compatible" with NRC regulations. *Id.* §2021(g); S. REP. No. 870, 86th Cong. 1st Sess. 11 (1959). Thus, Congress intended that the limited regulatory authority assumed by states pursuant to a Section 274 agreement with the NRC should not conflict with federal regulation or impair the development of atomic energy. *See Pacific Gas & Electric Co.*, 461 U.S. at 208-209; 42 U.S.C. §2021(g); S. REP. No. 870 at 11.

The foregoing history of atomic energy legislation demonstrates Congress' strong intention in the Atomic Energy Act to encourage and promote development of the peaceful uses of atomic energy. If NRC licensees operating in full compliance with NRC radioactive emissions standards may be subjected to state tort liability for injuries and property damage allegedly caused by authorized emissions, the important purpose of the Atomic Energy Act of promoting the development of peaceful applications of atomic energy will be frustrated. Institutions and private companies that develop atomic energy applications and

put them to use for the public good will be discouraged from continuing their operations. Nuclear research institutions, producers of nuclear medicine products, hospitals that administer nuclear medicine, electric utilities that use nuclear power to serve their customers, to name only a few, may choose to curtail or abandon the development and use of atomic energy applications. Such an outcome would be counter to the Atomic Energy Act's express purpose of encouraging and promoting peaceful applications of atomic energy for the benefit of the United States by improving the general welfare, increasing the standard of living, and strengthening free competition in private enterprise.

Broad public policy concerns are at stake in this case. The use of atomic energy in the diagnosis and treatment of disease, the generation of electricity, and the improvement of agriculture are some of the great accomplishments of the atomic age. The Missouri court's ruling is inimical to the further development and use of atomic energy for these and other purposes. If the court's decision is allowed to stand, the potential multiplicity of lawsuits faced by persons and institutions in the field of atomic energy could impede and perhaps prevent further progress in the development and use of atomic energy for peaceful purposes.

Congress and the Executive Branch have determined that the development and use of atomic energy are in the national interest. Congress continues to fund the Department of Energy's (DOE) atomic energy programs. For fiscal year 1986, Congress appropriated $23.3 million for the DOE Nuclear Medicine Applications Program. *Department of Energy Fiscal Year 1987 Budget: Hearings on H.R. 2959 Before the Subcomm. on Energy and Water Dev. of the House Appropriations Comm.*, 99th Cong., 2d Sess. 1 (1986) (Statement of Stanley J. Goldsmith,

M.D. on behalf of the Society of Nuclear Medicine and the American College of Nuclear Physicians); *see* Energy and Water Development Appropriations, Pub. L. No. 99-141, 99 Stat. 572-576 (1985). In addition, Congress appropriated a total of $377,625,000 for DOE's civilian nuclear energy research and development programs in 1986. *See* H.R. Rep. No. 99-307, 99th Cong., 1st Sess. 39-55 (1985); Energy and Water Development Appropriations, Pub. L. No. 99-141, 99 Stat. 572-576 (1985). These programs include the Light Water Reactor Program, Advanced Reactor Research and Development, and the Water Cooled Breeder Reactor Program. Under these and other atomic energy programs, DOE works with scientific institutions and private industry to develop new and improved uses of atomic energy for nuclear medicine, electricity generation, and other purposes. This support in Congress and the Administration for atomic energy development, even during a period of severe federal budgetary constraints and cost-cutting measures, demonstrates that Congress and the Administration believe that progress in atomic energy applications is important to the nation.

Nuclear medicine has many significant applications, including diagnosis and evaluation of heart disease, cancer, infant disorders, Alzheimer's disease and mental disorders. Radiopharmaceutical producers such as the petitioner, Mallinckrodt, Inc., make possible the practice of nuclear medicine. There are only a few such producers in the United States.[2] If these producers are subjected to

[2]There are only a handful of radiopharmaceutical manufacturers in the United States. The major companies are:

AMERSHAM CORPORATION
2636 S. Clearbrook Drive
Arlington Heights, IL 60005

DU PONT COMPANY
Diagnostic Imaging Division
331 Treble Cove Road
No. Billerica, MA 01862

unlimited tort liability for radiation injuries allegedly caused by activities carried on in the normal course of business in compliance with stringent federal safety standards for radioactive emissions, the producers may be forced to abandon their operations. The liability risk and the cost of liability insurance may prove too great to permit these companies to continue producing radiopharmaceutical products, which are the tools of nuclear medicine. Without the products that these companies provide, hospitals and other institutions now practicing nuclear medicine will be unable to continue to offer their many diagnostic and therapeutic nuclear medical services. Research and development in the field of nuclear medicine may also be harmed by the lower court's ruling. Research institutions may be forced by the specter of unlimited tort liability to reduce or discontinue their work to identify and develop new and better medical uses for radioactive materials. This result would be devastating to the health and welfare of the people of the United States who have come to depend on the health care benefits that nuclear medicine provides.

The negative impact of the Missouri court's decision is not limited to the field of nuclear medicine. Every industry that uses radioactive materials for civilian applications is threatened by the court's decision. Electric utilities with nuclear power plants generating electricity for the nation,

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MALLINCKRODT, INC.
Diagnostic Products Group
675 McDonnell Blvd.
P.O. Box 5840
St. Louis, MO 63134

MEDI-PHYSICS, INC.
4050 Lakeside Drive
Richmond, CA 94806

SQUIBB DIAGNOSTICS
P.O. Box 191
New Brunswick, NJ 08903

SYNCOR INTERNATIONAL CORPORATION
12847 Arroyo Street
Sylmar, CA 91342

CIS USA (manufacturers for SYNCOR)
1983 Marcus Avenue
Lake Success, NY 11042

hazardous waste managers treating and disposing of the nation's nuclear debris, institutions developing nuclear agricultural techniques such as food irradiation, and research facilities exploring better ways to use atomic energy in these and other endeavors will all feel the effects of the lower court's ruling. Without protection from unlimited tort liability arising out of activities carried on in compliance with federal safety standards for radioactive emissions, many of these industries may be forced to reduce or abandon their services to the public. Such a result would be counter to the national interest and detrimental to the welfare of the people of the United States.

B. Subjecting NRC Licensees to State Tort Liability When Such Licensees are Operating in Compliance With Federal Emissions Standards Conflicts With NRC Regulations and Imposes an Unnecessary Burden on the Atomic Energy Industry

Many members of the Society and the ANS are licensed by the NRC to possess nuclear materials or to operate nuclear facilities, and many other members are employed by licensed institutions or companies.[3] As a condition of their licenses, these licensees are subject to a stringent federal regulatory regime for nuclear safety.[4] Imposing state tort liability on NRC licensees that operate in compliance with this detailed and pervasive federal regulatory scheme con-

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[3]The Atomic Energy Act of 1954 and implementing regulations contain detailed licensing requirements for persons engaged in the use of nuclear materials and the operation of nuclear facilities. *See* 42 U.S.C. §§2073, 2092, 2093, 2111, 2133, 2134 (1982); 10 C.F.R. Parts 30, 40, 50, 70 (1985).

[4]*E.g.*, 10 C.F.R. §20.2 (1985) (NRC radiation protection standards apply to all licensees).

stitutes unnecessary and burdensome state regulation of nuclear safety matters in conflict with NRC's nuclear safety standards.

The NRC requires its licensees to comply with extraordinary detailed regulations governing every aspect of nuclear health and safety.[5] NRC's regulations governing radiation exposure limits are of particular relevance to this case. These regulations, codified at 10 C.F.R. Part 20 (1985), protect nuclear workers and the general public from the effects of radiation by establishing limits on the dose of radiation and the amount of radionuclides that may be released on-site at a nuclear facility and off-site into the environment. Specific limitations on hourly and weekly radiation levels surrounding licensed facilities are set forth in 10 C.F.R. §20.105(b) (1985). Maximum permissible concentrations of radionuclides in the air and water outside of a licensed facility are set forth in 10 C.F.R. Appendix B, Table II (1985). Licensees must comply with these stringent safety standards in conducting licensed activities. 10 C.F.R. §20.2 (1985).

In addition to these specific radiation limits, Part 20 imposes a second level of protection for workers and the general public in 10 C.F.R. §20.1(c) (1985). This section requires licensees to make every reasonable effort to maintain radiation exposures and releases of radioactive effluents "as low as reasonably achievable" (ALARA). The ALARA concept is based on the fact that licensees generally keep exposures to radiation and releases of radioactive effluents well below the Part 20 limits. *See* 35 Fed.

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[5]NRC's regulations governing the possession, use, processing, storage, transfer, packaging, and disposal of nuclear materials constitute an extensive regulatory scheme for nuclear health and safety. *See* 10 C.F.R. Parts 0-170 (1985).

Reg. 18,385 (December 3, 1970) (AEC comments on ALARA regulation). By requiring licensees to maintain exposure limits and effluent limits as low as reasonably achievable, the ALARA regulation helps to ensure that actual exposure and effluent levels are below the Part 20 limits.

NRC's radiation safety standards represent a conservative approach to radiation protection. *See, e.g.*, 25 Fed. Reg. 8595 (September 7, 1960). *See also Johnston v. United States,* 597 F. Supp. 374, 390-392, 423 (D. Kan. 1984). Scientific and medical evidence indicates that the lowest radiation exposure levels known to cause physical injuries are many times higher than the Part 20 limits. *See Johnston v. United States,* 597 F. Supp. at 390-392, 423. Thus, NRC's radiation safety regulations provide more than adequate protection for workers and the general public against health effects from radiation.

Subjecting NRC licensees who are operating in compliance with NRC radioactive effluent regulations to state tort liability constitutes the imposition of more stringent radiation protection standards than the standards required by NRC regulations. This Court has stated that "regulation can be as effectively asserted through an award of damages as through some form of preventive relief." *San Diego Building Trade Council v. Garmon,* 359 U.S. 236, 247 (1959). State law damages awards would permit juries to impose on licensees a "zero release" regulatory standard, since licensees could avoid the risk of liability only by eliminating all radioactive emissions from their facilities.

The NRC has determined that a zero release standard is unnecessary to protect public health and safety. *See* 10 C.F.R. Part 20. *See also Johnston v. United States,* 597 F.

Supp. at 390-392, 423. NRC's regulations contain a substantial "margin of safety" and are based on the recommendations of leading institutions that are authoritative in the field of radiation protection.[6] NRC's safety regulations have an excellent success record. Even the Three Mile Island accident, the most serious nuclear accident in U.S. history, has not had a significant effect on the physical health of individuals living and working near the reactor.[7] More stringent state standards would not only conflict with NRC's fully adequate standards, but would be completely unnecessary and burdensome to industry. Arbitrary state radiation standards imposed by juries would inject uncertainty and confusion into the nuclear regulatory system, since NRC licensees would be subjected to conflicting regulatory systems at the federal and state levels. Such a scenario would have a profound negative impact on the atomic energy industry, and on research and educational activities related to the industry.

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[6] *See* 40 Fed. Reg. 58,847 (December 19, 1975) (10 C.F.R. Part 20 ALARA regulations are based on recommendations of International Commission on Radiation Protection); 25 Fed. Reg. 8595 (September 7, 1960) (10 C.F.R. Part 20 revisions containing "considerable margin of safety" are based on recommendations of National Council on Radiation Protection).

[7] *See* G. Tokuhata and E. Digon, *Cancer Mortality & Mobidity (Incidence) Around TMI* 24 (1985); *Report of the President's Commission on the Accident at Three Mile Island* 12 (1979).

CONCLUSION

The petition for a writ of certiorari to the Missouri Court of Appeals should be granted.

Respectfully submitted,

L. Manning Muntzing*
Robert J. Ross
James R. Shoemaker

Doub & Muntzing, Chartered
1875 Eye Street, N.W.
Suite 775
Washington, D.C. 20006
(202) 467-6460

Attorneys for Amici Curiae

SOCIETY OF NUCLEAR MEDICINE, INC.
AMERICAN NUCLEAR SOCIETY

**Counsel of Record*

Of Counsel:

James R. Heelan
Resident Counsel

AMERICAN NUCLEAR SOCIETY
555 N. Kensington Avenue
La Grange Park, IL 60525
(312) 352-6611

May 17, 1986